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10/511,350

10/15/2004

James Barder

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WASHINGTON, DC 20005

EXAMINER

NGUYEN, CAMTU TRAN

ART UNIT

PAPER NUMBER

3772

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/511,350

Applicant(s)

BARDER, JAMES

Examiner

Camtu T. Nguyen

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☒ Claim(s) 9 and 18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

This Office Action is responding to applicant's amendment filed on 11/16/2007. Claim 1 has been amended.

Applicant's comments directed to disqualifying the Kemp reference as a prior art are acknowledged.

Applicant's comments directed to the objection applied to claims 3 & 10-18 are acknowledged, thus, such objection has been vacated.

Applicant's comments directed to 112 1st paragraph rejections, applied in the previous Office Action, have been carefully considered and acknowledged, thus, such rejections have been vacated.

### ***Claim Objections***

Claims 9 & 18 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, claim 9 recites subject matter therein that does not further limiting the subject matter of previous claim 8.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 9, and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, claim 1 reciting two scenarios, the vasodilator active compound in both of which are immiscible with the lubricant. The last paragraph in applicant's specification supports "the vasodilator active compound is disposed on the condom surface in a form or within a composition which is immiscible with the lubricant", such disclosure presents vasodilator active compound in two scenarios: (1) in a form or (2) within a composition. A broad and reasonable interpretation of the limitation is interpreted that only in the second scenario is the vasodilator active compound immiscible with the lubricant. With regards to claims 9 and its dependent claim 18, the specification lacks the support for the limitation of claim 9. Specifically, claim 9 recites the vasodilator active compound comprises an organic nitrate applied as a layer/coating in a polar elastomer in solution, such recitation is in contrary to the specification on page 7 (last paragraph) and page 8 (first paragraph) wherein it supports the suitable condom materials would include polar elastomer applied to the condom vasodilator active compound such as organic nitrates (ex: glyceryl trinitrate) should the vasodilator-containing layer is formed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 8-12, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crosby et al (U.S. Patent No. 6,737,084). Crosby et al discloses a composition and methods for treating female sexual response. Column 5 lines 29-50 discloses a composition administered by a condom by applying the composition to the condom prior to use in combination with other lubricants. Crosby further discloses that the same composition can further comprise other active agents including vasodilators agents which increase vaginal lubrication).

With regards to claim 1 reciting the vasodilator active compound is immiscible with the lubricant, applicant discloses in the last paragraph on page 2 supporting the condom of either natural rubber or of synthetic rubber-like material and any lubricant used therein, immiscible with vasodilator active compound. The Crosby et al reference discloses a male condom in column 5 lines 29-31 but does not explicitly state that the condom is of latex material or synthetic rubber-like material, however, such latex/synthetic rubber-like material with lubricant is common in the art of condoms, as evidenced by U.S. Patent No. 4,817,593 to Taller et al. Therefore, applying the Crosby et al composition on Taller et al's latex condom, would indeed render the vasodilator immiscible with the lubricant, which is consistent with applicant's disclosure.

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With regards to claim 2, the Crosby et al reference discloses the claimed invention except for the compound is disposed towards the open end of the condom. It would have been obvious to one having ordinary skill in the art at the time the invention was made to dispose it towards the open end of the condom for purposes of being in the vicinity of the clitoris, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

With regards to claim 3 reciting a carrier with which the vasodilator active compound is miscible, the Crosby et al discloses a carrier that is pharmaceutically formulated with the composition (column 5 lines 59-67 & column 7 lines 1-18), rendering the two are miscible.

With regards to claim 8, the Crosby et al reference discloses the composition which comprises one or more of the following ingredients: phosphodiesterase (PDE) inhibitors and equivalents thereof (column 1 line 35-36).

With regards to claim 9, applicant's specification on page 2 (last paragraph) and page 3 (first paragraph) discloses suitable materials of condom (latex or synthetic rubber-like) would include polar elastomers applied to condom for the vasodilator active compound such as organic nitrates (example: glyceryl trinitrate). The Crosby et al reference discloses the composition produces one or more pharmacological effects: increases in localized nitric oxide (column 1 lines 36-39). With that in mind, compounds that release nitric oxide upon being metabolized include widely used glyceryl trinitrate. Therefore, a condom of latex material would include a layer/coating of organic nitrate or glyceryl trinitrate applied thereon, which is consistent with applicant's disclosure.

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With regards to claims 10-12, 17, and 18 reciting the active compound optionally together a skin penetration enhancer, the Crosby et al reference the skin enhancer in the form of Azone (column 6 lines 39) and miscellaneous ingredients such as liquid glucose, magnesium chloride, and even starch as a liquid medium and a thickening agent (column 6 lines 52-55).

Claims 4 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crosby et al (U.S. Patent No. 6,737,084) and further in view of Moench et al (U.S. Patent No. 5,592,949). Crosby et al, as presented above, discloses all elements recited in these claims including a lubricant but does not suggest the lubricant is buffered between 3 and 5 pH. Moench et al discloses an acidic buffered gel having a pH between 3 and 5 (column 12 lines 15-20) and this gel can also be used with a condom (column 15 lines 3-6). Therefore, it would have been obvious to one skilled in the art to utilize a lubricant buffered between 3 and 5 pH, as taught by Moench, as such would prevent hydrolysis of the active composition.

Claims 5-7, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crosby et al (U.S. Patent No. 6,737,084) and further in view of Osterberg (U.S. Patent No. 6,651,667) in view of Schwartz (U.S. Patent No. 5,626,149). Crosby et al, presented above, discloses all elements recited in these claims except for the textured/undulating region to the external surface as recited in claim 5. The Osterberg reference discloses a male condom (10) comprising textured/undulating region on the external surface of the condom (10) in the form pockets (26). Therefore, it would have been obvious to one skilled in the art to modify the Crosby et al's condom to include texture/undulated region on the external surface of the condom in the form of pockets (26), as disclosed by Osterberg, for purposes of providing stimulation.

With regards to claim 6, the Osterberg's pockets (26) are filled with material (column 5 lines 23-28) but are not filled with a vasodilator medication therein. The Schwartz condom discloses fluid retaining chamber (4) storing therein. Therefore, it would have been obvious to one skilled in the art to modify the material in the Osterberg's pocket to now filled with the vasodilator medication therein, as taught by Schwartz for purposes of fulfilling a function, that is to release the medication upon a necessity.

With regards to claim 7, applicant's specification on page 2 (last paragraph) discloses the condom material formed of either natural rubber latex or a synthetic rubber-like material, of which material should be miscible with the vasodilator. With that in mind, the Osterberg reference discloses the condom (10) is manufactured of latex rubber but also can be manufactured from elastomeric materials such as urethane polymers, rubber, synthetic rubber, or non-allergic plastic (e.g. surgical plastic), see column 4 lines 7-11. Therefore, the Osterberg's textured/undulating region is formed from latex rubber material, of which the same material condom is formed, which is miscible with the vasodilator, as disclosed by applicant's specification on page 2 (last paragraph).

With regards to claims 14 & 15, reciting the skin enhancer in the form of Azone (column 6 lines 39) and miscellaneous ingredients such as liquid glucose, magnesium chloride, and even starch as a liquid medium and a thickening agent (column 6 lines 52-55).



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***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 571-272-4799.

The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Camtu T. Nguyen/  
Examiner, Art Unit 3772

  
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3/3/08